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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,365	11/12/2001	Carol W. Readhead	18810-81606	9234

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NIKOLAI & MERSEREAU, P.A.
900 SECOND AVENUE SOUTH
SUITE 820
MINNEAPOLIS, MN 55402

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,365	READHEAD ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *135-144,152-161 and 168-176* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *135-144, 152-161, 168-176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 09/191,920, filed November 13, 1998, which claims benefit to provisional application 60/065,825 filed November 14, 1997.

Applicants' amendment filed October 12, 2004, has been received and entered. Claims 145-151, 162-167 and 177-182 have been canceled. Claims 135, 152, 154, and 168 have been amended. Claims 135-144, 152-161 and 168-176 are pending.

Election/Restriction

Applicant's election of Group I, claims 145-151, 162-167 and 177-182, was acknowledged. No new arguments have set forth in the instant amendment.

Claims 135-144, 152-161 and 168-176 are pending and currently under examination as they are drawn to a non-human transgenic vertebrate.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Claims 135-144, 152-161 and 168-176 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 152 and 168 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to the claims to delete the term "trait" has addressed the basis of the rejection. It is noted that the claims still recite the term "desired" which is relative to an individuals need or want, and it is noted that this term is being interpreted simply as being very broad encompassing any gene or gene product since there is probably some desire in the art of any gene product.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 135, 152, and 168 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, the amendment that recites that "the polynucleotide is one that does not encode oncogene products" is considered new matter. Review of the specific portions of the specification indicated as supporting the amendments does not provide literal support for the claimed amendment. A review of the remaining portions of the specification do not provide

literal support for the amendment neither. To the contrary, the specification teaches that any gene product (claim 135, step a), or more specifically any that is "desired" (see claim 152 for example) for study in a transgenic animal would be considered as part of the claimed invention. The specification teaches that any transgene construct can be made and delivered with the disclosed methodology and there is no specific teaching in the instant specification to exclude any particular gene product from the scope of the claimed invention.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 135, 152 and 168 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to

determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 135-144, 152-161 and 168-176 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 135 of copending Application No. 10/074,945.

Applicants' indication that a terminal disclaimer will be submitted at the proper time, and at this point it us unwarranted is acknowledged. See Applicants' amendment, page 10.

The claims of 10/074,945 are still pending and considered obvious over the instantly claimed invention. Since the claims have not been cancelled, it appears that a terminal disclaimer could be considered warranted at this point in prosecution. Again, although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed transgenic vertebrates would necessarily result in practicing the method of claim 135. For example, claim 168 specifically recites the same method steps of claim 135. It is

noted that the preamble of claim 135 is generally directed to gene therapy, however the outcome and animal that results from practicing the claimed method would inherently be the same as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims135-144, 152-161 and 168-176 stand rejected under 35 U.S.C. 102(e) as being anticipated by Brinster *et al.* (US Patent 5,858,354) and Deboer *et al.* (US Patent 5,741,957).

Applicants argue that the amendments to the claims have differentitated the claimed invention from that disclosed by Brinster *et al.* and Deboer *et al.* In particular Applicants note that neither reference teaches that a viral vector was used in the construction of the transgenic animals, nor in the case of Deboer *et al.* teach germ cell manipulation to produce the claimed transgenic animal. Further, it is noted that the introduction of a viral vector into the testis would

result in a different pattern of insertion, and could be distinguished from that produced by other methods. See Applicants' amendment, pages 10-11.

Examiner acknowledges that claims 135-144, 152-161 and 168-176 are generated as product by process, however these process steps do not exclude transgenic animals made by other means since the method steps do not result in a materially different transgenic animal than that produced by the methods of either Brinster *et al.* or Deboer *et al.* Applicants statements that the methods would result in a different animal, however neither the specification nor the art of record indicate this to be fact. In addition to the absence of supporting the assertion, the specification provides no teaching that this "pattern of insertion" occurs, or any guidance to distinguish this unique property of the transgenic mammal from that obtained from any other methodology. There is not evidence that the resulting animals would be different as a consequence of practicing the different methods known in the art. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

As stated in the previous office action, Brinster *et al.* teaches a method for making a genetically altered transgenic animal wherein germ cells are genetically altered *in vitro* an subsequently transplanted back into the seminiferous tubules. The allowed claims specifically set forth transducing the cell type of spermatogonia, however the specification provides for other male germ cells to be collected and used in the claimed methods. Practicing the methods claimed by Brinster *et al.* result in a transgenic animal comprising germ cells that have been genetically modified with a transgene. Deboer *et al.* teach a method of making a transgenic

bovine whose genome comprises an transgene that is preferentially expressed in the mammary gland (see abstract). It is noted that the methods of Deboer *et al.* result in a transgenic animal in which both the germ cells and somatic cells contain the transgene, however the instantly pending claims do not exclude this possibility. Importantly, dependent claims directed to progeny will necessarily comprise the transgene in both the somatic cells and germ cells if produced by mating.

Where, as here, the claimed and prior art products are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw,* 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). It is maintained that an transgenic animal made by either the method of Brinster *et al.*, Deboer *et al.* or that set forth in the instant application would be distinguishable since the resulting animal could each have the same resulting transgene of an encoded gene product in operable linkage with a promoter.

Claims 135-144, 152-161 and 168-176 rejected under 35 U.S.C. 102(b) as being anticipated by Leder *et al.* (US Patent 4,736,866) is withdrawn.

The amendment to the dependent claims to exclude the expression of oncogenes has differentiated the claimed invention from that of Leder *et al.* that teach non-human transgenic mammals whose genome comprises an activated oncogene (see abstract).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach